Implementation of FDA Menu Labeling Regulation at Made-to-Order Food Establishments Relies on Knowledgeable Employees

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Emily Clare McMullin

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ABSTRACT

Consumption of food outside the home accounts for one-third of recommended daily calories and may contribute to rising obesity rates. Menu labeling may be a strategy to influence consumer behavior. The Food and Drug Administration (FDA) developed menu labeling requirements which are not yet mandatory. This case study describes implementation from employee perspectives in one made-to-order food establishment. Four data sources were triangulated – employee interviews (n=15), key informant interviews (n=3), organizational documents, and informal participant observation. Employees received varying degrees of training, but only six of fifteen employees were able to calculate total calories accurately (+/- 20 calories) for a hypothetical order. Employees felt confident in their ability to answer nutrition questions from customers, but relied on supervisors and managers. Monitoring of preparation practices mimicked other organizational practices, but employee knowledge was not monitored. This case study revealed barriers to successful implementation of menu labeling in the complex made-to-order context.

BIOGRAPHICAL SKETCH

Emily McMullin, RD is a graduate student in the MS program in the Division of Nutritional Sciences at Cornell University. She is currently completing her masters in nutritional sciences at Cornell University in Ithaca, NY and is expecting to graduate in August 2017. Prior to that, she completed the dietetic internship at Cornell University in June 2016, including its clinical and management rotations at the University of Rochester Medical Center. Emily has served as a graduate teaching assistant in an entry level culinary lab which empowers students to apply basic cooking techniques, food science principles, and nutrition concepts to their daily lives. She also has experience working in retail dietetics with supermarkets and in worksite and student wellness programs. Emily is interested in the synthesis and dissemination of nutrition messages by food companies to enable customers to make healthy dining decisions at food establishments. More specifically, her research examines employees' perceptions of calorie labeling regulations in supermarkets and their relation with implementation. Emily is a member of the Academy of Nutrition and Dietetics and the New York State Academy of Nutrition and Dietetics.

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LIST OF ABBREVIATIONS

FAFH – food away from home

FAH – food at home

ACA – Patient Protection and Affordable Care Act

FDA – United States Food and Drug Administration

BMI – body mass index

FDA regulation – the FDA menu labeling requirements as outlined by the regulation titled *Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments*

EM – Early Market, pseudonym used for the supermarket organization that was an early adopter of the FDA regulation

KAP – Knowledge, Attitudes, Practices model of Rogers' Theory of Diffusion of Innovations

Complete nutrition information – nutrition information beyond calories that must be provided by the food establishment in writing upon request, including total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fibers, sugars, and protein

ECM – initials of the primary researcher

RD – registered dietitian

Chapter 1: Background and Literature Review

The prevalence of obesity and overweight in the United States has increased significantly from 1976 to the mid 2000s (1), while more recent data from 2009-2010 demonstrated that the increase in obesity has started to slow (1). Despite the deceleration of this trend, more than two thirds of adults are overweight or obese which are known risk factors for the development of chronic diseases (2). Dietary and lifestyle patterns play a crucial role in the development of obesity and the subsequent development of chronic diseases.

Consideration of food consumption at places outside the home is an important factor in the multifaceted context of dietary patterns. In 2015, the average household spent 43% of their food expenditures on food away from home (FAFH) (3). FAFH expenditures includes the total cost of all meals, snacks, and nonalcoholic beverages at fast food, take-out, delivery, concession stands, buffet, cafeteria, full service restaurants, vending machines, and mobile vendors (4). From 1977 to the mid 2000s, the share of calories consumed from FAFH increased from 18% to 32%, which corresponded to an increase in household expenditures on FAFH (5). This increase in caloric intake from FAFH mostly occurred in full service and fast food restaurants (5). Furthermore, FAFH is generally higher in calories and lower in nutritional quality than food prepared at home and contributes to a reduction in diet quality (5). More specifically, FAFH is higher in saturated fat and sodium, and lower in fiber and calcium (excluding school foods which were highest in calcium) than foods at home (FAH), particularly at fast food restaurants (5). A recent systematic review found that there is a positive association between eating out and weight gain (6), contributing to the development of obesity. Through its role in weight gain and development of obesity, FAFH also has the potential to increase risks of developing chronic diseases.

Context for Menu Labeling Recommendations

Chronic diseases are responsible for substantial public and private economic burdens due to high medical costs associated with care and management of chronic diseases. Menu labeling is a quantitative or qualitative indicator of nutrient composition of food items on menus at food establishments. The provision of nutritional information via menu labeling may influence food purchasing behavior, and could therefore help combat the burden of obesity and chronic diseases (7). Common forms of quantitative menu labeling include the provision of calories and other nutrient amounts on menus (8). Qualitative menu labeling is the use of symbols, such as traffic light symbols, on menus to indicate the nutritional quality of a food item at restaurants (8). Menu labeling has been proposed in recent years as a potentially cost-effective way to influence consumers' food choice decisions in an effort to decrease consumption of calories and influence the risks of developing obesity and chronic diseases (7).

Currently, food service establishments in most parts of the country are not required to disclose nutrition information about menu items, with some notable exceptions in California, Vermont, and some counties in Maryland, Washington, and New York (9). The lack of nutrition information available to consumers for FAFH prevents consumers from making informed decisions about their food when eating out. Following this logic, the Patient Protection and Affordable Care Act of 2010 (ACA) empowered the United States Food and Drug Administration (FDA) to regulate menu labeling requirements at food service establishments (10). The proposed FDA menu labeling requirements (hereafter referred to as 'FDA regulation') mandate quantitative menu labeling, with calories on menus and additional written nutrition information available upon consumer request (11). Specifics of the FDA regulation will be discussed in Chapter 2.

Influence of Menu Labeling on Consumer Purchasing Behavior

Since the drafting of the FDA regulation in 2010 there has been extensive research on consumers' behavior in localities where menu labeling mandates preceded 2010. A systematic review conducted by Swartz et al. examined seven peer-reviewed experimental and quasi-experimental studies that examined consumer purchasing behavior in the presence of calorie labeling compared to no labeling (12). The systematic review concluded that there was little to no effect of menu labeling on consumer purchasing behavior in both laboratory and real world settings and that several studies reported that not all participants were aware of the calorie labeling even when present (12).

A systematic review conducted by Fernandes et al. examined the effect of diverse quantitative and qualitative menu labeling formats on consumers' food purchasing behavior in real-life settings (8). The systematic review concluded that calorie labeling of menu items was not an effective means of changing consumer purchasing behavior, whereas qualitative menu labeling influenced consumer behavior in some settings and sometimes only among a sub-group of participants (8). Other recent systematic reviews and meta analyses found similar minimal or null effects of calorie menu labeling on consumer behavior (13–15).

There is a surprising absence of research examining the role of employees in implementing menu labeling. Prior research has suggested that workers which engage in activities related to government policy are instrumental in policy implementation; thus the perspective of food service employees is important in understanding the implementation of the FDA regulation (16). Employees at food service establishments ultimately act either to uphold or undermine the integrity of menu labeling, perhaps unknowingly, by engaging in food preparation practices that are congruent or incongruent with label nutrition information. Employee awareness

of menu labeling, knowledge of proper food preparation practices to uphold menu labeling, and their own nutrition knowledge all may influence implementation of menu labeling.

Knowledge of Food Service Workers

Nutrition knowledge of the general population in the United States is low. In a survey conducted by the International Food Information Council, less than one third of U.S. adults surveyed understood that all sources of calories equally contribute to weight gain (17). Furthermore, surveys of adults following an eight-week health marketing campaign demonstrated that less than one third of adults correctly identified the recommended number of calories per day, and those with lower education levels were less likely to identify the correct calorie recommendation (18).

Workers earning low hourly wages predominantly have low education; 46.6% of these workers have only a high school diploma or less (19). This statistic jumps to 69.4% when including hourly wage workers who started college but did not attain a degree (19). Food service employees make up the highest percent of hourly paid workers earning at or below the federal minimum wage among service occupations (19). In food service occupations, no post-secondary education is needed, and many entry-level jobs do not require a high school diploma (20). Yet, with the introduction of the FDA regulation employees may be expected to answer questions pertaining to the nutritional content of menu items.

Effectiveness of nutrition education is pertinent to the study at hand because (1) employees must receive nutrition education training on menu labeling in order to answer customer questions, (2) employees reflect a sub group of the population that must interpret the information when making their own food decisions, and (3) these employees are likely to have

low educational attainment and therefore low levels of baseline nutrition knowledge. There are data to support the positive impact of nutrition education on low-income populations (21–26). Research has shown that low income individuals with low nutrition knowledge at baseline were able to apply nutrition education information presented to them and positively influence dietary habits post-intervention (23). Furthermore, nutrition education has been shown to impact significantly food behaviors such as reading nutrition labels, eating breakfast, and meal planning (21–23). Other nutrition education intervention programs measure the movement in stages of change and intention to change (24,26), recognition of education messages (24), and changes in body mass index (BMI) (25), all of which showing positive improvement.

There is a paucity of data on the impact of nutrition education in populations of food service employees. One large study examined the effectiveness of food safety training in food service employees using a quasi-experimental design with observations of behavior before and after education and pre-post intervention knowledge tests (27). The study examined composite and overall knowledge and behavior related to handwashing, cross contamination, and time and temperature control. The study found that overall knowledge and behavior improved significantly, but only handwashing knowledge and behavior increased significantly when food safety practices were examined independently, whereas behaviors related to cross contamination and time and temperature control did not improve significantly (27). In this population of food service employees, the study demonstrated that employee training can increase knowledge and behaviors but knowledge alone is insufficient to improve behavior (27). Nutrition education and training of food service employees in the context of FDA regulation implementation is important for provision of accurate nutrition information to consumers.

Aim and Introduction to the Manuscript

This thesis is a qualitative case study description of the implementation of FDA menu labeling regulation *Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments* in a made-to-order food establishment within a retail supermarket from the perspective of employees (7). This study draws on the scholarly literature related to changes in food purchasing behavior, implications of menu labeling on food purchasing behavior, and the role of nutrition education in behavior change. This case study was guided by the knowledge, attitudes, practices (KAP) adaptation of Rogers' theory of diffusion of innovations (28,29). Four sources of data – formal printed and electronic information, informal participant observation, employee interviews, and key informant interviews – were triangulated to describe the process of implementing the FDA regulation in one made-to-order food establishment. By describing this process from the employee perspective, organizations can better understand and address the concerns of the employees who are implementing the regulation through their interaction with consumers. Furthermore, the description of the process of implementation prior to the mandatory compliance date of the regulation can serve as a model for made-to-order food service organizations that have not yet implemented the FDA regulation. Chapter 2 will provide an in-depth description of the scientific approach, results, and brief discussion of the research. Chapter 3 will expand upon intriguing discussion points drawing from the results of the thesis, and developing implications for organizational implementation of regulations, public policy, and future research.

The Conceptual Framework

A conceptual model (Figure 1) was created based on Roger's Diffusion of Innovations Theory (28). The theory is used to describe the flow of information in an organization when an innovation is introduced by an outside source. The knowledge, attitudes, practices (KAP) model was adapted for this research (29). The KAP model does not include the decision-making step from Roger's original Diffusion of Innovation theory, and this exclusion is appropriate in the study context because the implementation of menu labeling requirements is not optional for supermarkets or their employees (29).

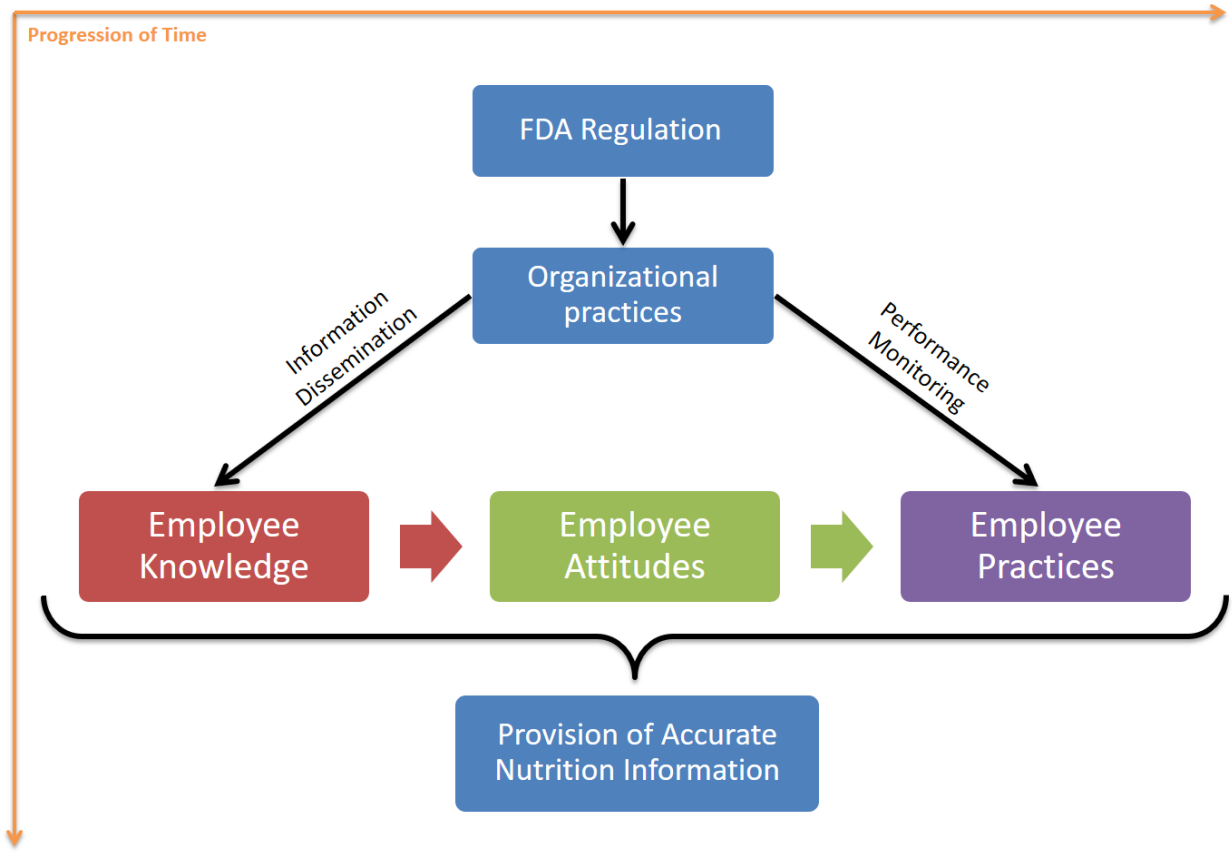

Figure 1. The conceptual model. The KAP model of Rogers' Theory of Diffusion of Innovations.

In applying the model to research, the introduction of the FDA regulation to food service organizations represents the innovation expected to diffuse. The research took place at Early

Supermarket (EM), which was an 'early adopter' of the menu labeling elements outlined by the FDA regulation (28). In the second level, EM disseminates information to employees primarily through training and distribution of organizational resources, and monitors employee practices related to the FDA regulation. The third hierarchical level explains the progression of understanding and implementation of menu labeling requirements by supermarket employees: beginning with employee knowledge relevant to implementation of the regulation, progressing to formation of employee attitudes of menu labeling requirements, and terminating in employee practices related to the regulation implementation. This level of the model is highly relevant to the description of the implementation process from the perspective of the employees.

In this model, organizational practices represent the primary step in the diffusion of innovations process within EM. Practices implemented by EM, including information dissemination pertaining to the FDA regulation and performance monitoring, may influence downstream implementation by employees. The organizational practice of training and dissemination of other pertinent information has the potential to influence employee knowledge as it relates to the FDA regulation. Performance monitoring procedures by the organization may influence the ultimate step of employee practices related to regulation implementation. The implementation of an innovation is more likely to be successful when organizations develop monitoring activities that include positive feedback and reinforcement for its members (30). This can manifest itself by providing information, support, motivation, and engagement in the behavior change throughout the diffusion of innovation process (30).

The first step at the employee level in the diffusion of this innovation involves innovators developing an awareness of, and gaining knowledge about, the innovation (28,29). This model posits that organizational information dissemination, particularly training and education related

to nutrition, and employee knowledge of the FDA regulation may play a role in the provision of nutrition information to customers.

Employee attitudes of the FDA regulation precede employee practices. This construct posits that employees must formulate their own opinions about the innovation and discern their role in implementation (29). Furthermore, the construct demonstrates that members of an organization must develop a positive sentiment toward the innovation for implementation to persist (29). In terms of the employees' roles in implementing the innovation in a made-to-order food establishment, the FDA regulation necessitates employees possess a certain skill level in answering consumer questions regarding nutrition content of food. As a result, employees' confidence in their ability to implement the FDA regulation by answering customer questions may be an important aspect of the model. An employee with high confidence in his or her ability to answer customer questions is more likely to develop a positive attitude toward the regulation, thereby increasing the chances that the employee will continue to the final step of implementation (28). The theory posits that employees in this stage of the diffusion process have adopted the innovation and consistently take actions toward implementing the innovation (28). The next chapter will provide more detail about the role of the conceptual model in guiding the research.

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Chapter 2: Implementation of FDA Menu Labeling Regulation at Made-to-Order Food Establishments Relies on Knowledgeable Employees

Introduction

Background

More than two thirds of adults in the United States are overweight or obese, contributing to higher risk for the development of chronic diseases (2). Dietary and lifestyle patterns play a crucial role in the development of obesity and chronic diseases, and consideration of food consumption at places outside the home is an important factor in the multifaceted context of these dietary patterns. In 2015, the average household spent 43% of their food expenditures on food away from home (FAFH) (3). From 1977 to the mid 2000s, the share of calories consumed from FAFH increased from 18% to 32% (5). Furthermore, FAFH is higher in calories, saturated fat, and sodium, and lower in fiber and calcium than foods at home (FAH), particularly at fast food restaurants (5). A recent systematic review found that there is a positive association between eating out and weight gain (6), which contributes to the development of obesity and potentially chronic diseases.

Chronic diseases are responsible for substantial public and private economic burdens due to high medical costs associated with care and management of chronic diseases (31). Menu labeling provides consumers with an indication of the nutrient composition of food items on menus. The provision of nutrition information by menu labeling at food service establishments may influence consumer food purchasing behavior, and could therefore help combat the burden of obesity (32). One common form of menu labeling is the provision of calories and other nutrient amounts on menus. Currently, food service establishments in most parts of the country are not required to disclose nutrition information (9). The lack of nutrition information available to consumers for FAFH prevents consumers from making informed decisions about their food

when eating out. Following this logic, the Patient Protection and Affordable Care Act of 2010 (ACA) empowered the United States Food and Drug Administration (FDA) to regulate menu labeling at food service establishments. The proposed FDA menu labeling requirements (hereafter referred to as 'FDA regulation') mandates calorie labeling on menus and availability of further nutrition upon consumer request in an effort to empower consumers to make more informed food decisions when eating out (32).

The FDA Regulation

The FDA regulation, *Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments* (32), requires all restaurants and similar retail food establishments with more than twenty locations to include calories on menus and menu boards, and display a succinct statement about total recommended calories per day. Additionally, establishments must be able to provide further nutrition information including total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, fibers, sugars, and protein in writing upon request for all regular menu items (hereafter referred to as 'complete nutrition information'), and include a statement notifying customers that complete nutrition information is available upon request (32). The FDA regulation excludes food establishments with fewer than twenty locations, as well as temporary menu items. However, supermarkets and made-to-order food establishments are among those that are covered by the regulation.

At made-to-order food establishments, such as sandwich shops, regulation compliance requires two levels of implementation. The first level of implementation requires food service employees to make sandwiches that are consistent with the nutrition information reported on

menus by following the standardized recipes. Failure to follow standardized recipes results in sandwiches with nutrient composition that does not match the menus, and thereby gives customers inaccurate nutrition information.

The second level of implementation requires employees to provide any requested nutrition information beyond the calories printed on the menus, and to answer any customer questions pertaining to the nutrition content of the sandwiches. The provision of nutrition information to customers is complicated by the highly variable nature of made-to-order sandwiches, so that the reported nutrition information may be incongruous with the sandwich the customer ordered. The FDA regulation accounts for the variability of made-to-order items by allowing organizations to report calorie ranges rather than a specific caloric amount (32). However, complete nutrition information still must be provided upon request and depending upon customer selections the ranges may encompass a wide range of values thereby rendering the information useless.

The FDA regulation is part of the ACA in 2010 (10), but the final rule was not released until December 2014 (32). During multiple comment periods from 2010 to July 2017 (33), the food service industry (most notably convenience stores, grocers, movie theaters and the pizza industry), responded with concerns about implementing the regulation and strongly urged the FDA to delay the compliance deadline (34–36). The FDA issued the Final Guidance on Menu Labeling in May 2016, mandated implementation by May 2017, and then delayed implementation to May 2018 (33). At the time of this writing, regulation compliance is still not mandatory.

Since the enforcement of the first menu labeling regulations in New York City in 2008, followed by other similar local regulations in discrete locations around the country, there has

been extensive research of consumers' behavior in response to menu labeling (8,12–15). However, very little research has looked at employees' roles in implementing such menu labeling.

The implementation of the FDA regulation within made-to-order food establishments is complex, and especially so for sandwich shop employees. The menu items in a made-to-order sandwich shop present countless permutations of sandwich options.

This chapter describes a case study that examined implementation of the FDA regulation on menu labeling in made-to-order sandwich shops in a supermarket chain in upstate New York (which will be identified by the pseudonym Early Market (EM)). This location was chosen due to its preemptive implementation of the regulation in August 2015, more than two years before the mandatory compliance date of May 2018. As such, EM exemplifies an 'early adopter' (28) and provides a lens through which to view one method of implementing the FDA regulation in a made-to-order context. This case study is primarily based on the perceptions of the employees, but also supported by perceptions of key informants, informal participant observation, and document analysis. The research is important to the larger question of regulation implementation because the employees that interact with consumers are often at the forefront of policy implementation, carrying out the procedures and practices that ultimately lead to the enactment of policy (16). Their perceptions are a defining piece of the multi-step process of regulation implementation.

Research Questions

This case study was guided by the knowledge, attitudes, practices (KAP) adaptation of Rogers' theory of diffusion of innovations. The conceptual framework (shown in chapter 1)

outlines organizational practices, information dissemination, and performance monitoring as constructs describing organizational actions, which feed into the constructs of employee knowledge, employee attitudes, and employee practices (29).

Four research questions were developed in relation to the aforementioned conceptual domains in order to investigate employee perceptions of the implementation of the FDA regulation.

1. How do organizational practices correspond to the implementation of the FDA menu labeling regulation?
    a. How does training and other organizational information dissemination support implementation of the FDA menu labeling regulation?
    b. How do organizations monitor implementation of the FDA menu labeling regulation?
2. How is employee knowledge of nutrition related to implementation of the FDA menu labeling regulation?
3. What roles do employee attitudes, including confidence, play in the implementation of the FDA menu labeling regulation?
4. How have employee knowledge and employee attitudes shifted in the first year of implementation of FDA menu labeling regulation?

Methods

Data Sources

This case study draws on four distinct components– formal printed and electronic information, informal participant observation, employee interviews, and key informant interviews. All data sources were triangulated to answer the research questions.

1. *Employee Interviews*

Fifteen sandwich shop employee interviews were conducted during November 2015 (n=6) and December 2016 (n=9). These employees were interviewed due to their role in directly implementing the FDA regulation via sandwich preparation and interaction with the customers.

Three stores were sampled using purposive selection to include a diverse customer base. One store was selected because it served a suburban, middle income neighborhood population,

one store served working professionals in an area populated with office buildings, and one store served a higher income customer base. Within the three purposively sampled stores, employees in the sandwich shops were convenience sampled based on their availability and willingness. All employee interviews took place during the day between 8 am and 5 pm.

Employees were interviewed using semi-structured, theory-guided qualitative inquiry. The interview questions were developed to investigate the conceptual domains of interest as they relate to the FDA regulation (Table 1). The in-depth nature of the qualitative inquiry optimizes the potential for data collection on employee perceptions. Qualitative interviews allow more time with participants and more exploration into their perceptions of the FDA regulation. Each of the interviews were recorded and transcribed verbatim. Employee interviews in 2016 included additional questions pertaining to performance monitoring and organizational information dissemination.

All employees also were asked to calculate an example calorie question (hereafter referred to as 'the calorie test'), in which the interviewer dictated a hypothetical customer sandwich order and asked the employee for help understanding the menu board and the calorie summation. A paper copy of the menu board with printed calorie information was provided to the employees for the calorie test. The information in the calorie test was used to assess objectively the employee practices related to the implementation of the FDA regulation. All employee interviews were recorded and transcribed verbatim.

Table 1. Key questions for employee interviews presented by conceptual domain.

Conceptual Domain	**Interview Questions** [a]
Organizational Practices	What resources do you have available to help you answer customer questions about nutrition information?
Information Dissemination	What kind of training have you received about the new sub menu boards?
	Have you received any education from EM about nutrition? What was the format? What information was presented?
Performance Monitoring	Are you corrected when another employee thinks you are doing something wrong? Are you recognized when you do something well?
	Has your understanding of the sub boards been evaluated?
Employee Knowledge	What can you tell me about the new menu boards?
	What nutrition information is available to customers?
Employee Attitudes	How well are you able to answer customer questions about the nutritional content of subs?
	What would help you feel more confident and able to answer customer questions about nutrition?
Employee Practices	If a customer had a question about the nutritional content of their sandwich, how would you explain it to them?
	Using information on the menu board, how many calories does a roast beef sub with provolone cheese, lettuce, tomato, mustard, and mayo have?

[a] bolded interview questions were asked only in 2016 interviews

2. *Key Informant Interviews*

Cross sectional interviews were conducted in January 2017 (n=3) with key informants involved in regulation implementation at the management level. Key informants were selected from the corporate office (n=1) and the stores from which the employees were sampled (n=2). All three key informants who were asked to participate accepted. Key informants were interviewed using a semi-structured theory-guided interview protocol with questions about organizational practices, and primarily pertaining to the monitoring of the regulation implementation (Table 2). Interviews were recorded and transcribed verbatim.

Table 2. Key questions for key informant interviews presented by conceptual domain.

Conceptual Domain	**Interview Questions**
Organizational Practices	What resources do the employees have to help them answer customer questions about nutrition information?
Information Dissemination	What kind of training do employees receive pertaining to the FDA regulation?
Performance Monitoring	What are your expectations of the employees in the implementation of the FDA regulation?
	How do you monitor the employee practices related to the FDA regulation?

3. *Formal Printed and Electronic Data*

Organizational documents were used as data sources about the organizational context and organizational practices related to the implementation of the FDA regulation. Printed documents included menu boards, nutrition reference guides, marketing materials, and nutrition programming materials. Menu boards are typically seen at fast food and fast casual restaurants in which menu items and associated information are displayed on large signs rather than individually distributed menus. The display of calorie information on menu boards at the EM sandwich shop was used as data. The nutrition reference guides contained the complete nutrition information that must be provided to customers upon request according to the FDA regulation, and this information was also available on the EM website. Marketing materials included documents that were disseminated by the organization to customers such as promotional catalogues and magazines. Nutrition programming materials included informational brochures on special diets, and nutrition messages disseminated on the EM website, in-store, and in marketing materials. The electronic data sources included messages and information displayed on the EM website.

4. *Informal Participant Observation*

The primary researcher (ECM) served as a dietetic intern at EM from August-November 2015. In this role, she collaborated with corporate nutrition and product labeling employees responsible for ensuring organizational compliance with the FDA regulation. Relevant experiences included conversations with corporate labeling and nutrition employees that helped to shape the research questions, strengthened the understanding of regulation implementation at the organization, and subsequently informed the development of interview questions. Furthermore, these interactions led to the identification of key informants and contributed to the purposive sampling of stores from which employees were sampled.

The participant observation involved informal reflection on experiences with the organization after serving as a dietetic intern. These experiences primarily informed the researcher about the culture and structure of the organization, and contributed to a basic understanding of the expectations of sandwich shop employees from the perspective of corporate managers.

Analysis

Employee interviews comprised the central source of data for this case study. All employee interviews were coded using provisional codes based on the conceptual framework, using Nvivo 11 software. Code definitions were refined throughout analysis in an iterative process, until descriptive codes were finalized and assigned in first cycle coding. In second cycle coding, descriptive codes were merged and organized, and emergent themes identified. Six transcripts (three from 2015 and three from 2016) were coded by a second independent coder; the kappa statistic was 0.86, which demonstrated high inter-rater reliability. Frequency and

content of descriptive coding was contrasted for employees interviewed in 2015 and 2016, and responses were observed to be consistent across years. Therefore, employee interviews from 2015 and 2016 were pooled in all results presented.

Organizational documents were examined to provide supporting data to augment, or provide context for, employees' perceptions. Reflections on participant observation provided a supplementary perspective on the culture and structure of the organization. And, key informant responses were used to support and/or contradict employee perceptions and therefore were coded using the same thematic codes developed during employee interviews. All data sources were triangulated to provide the richest description of the resultant themes within this case study. The study was exempted from review by the Cornell University Institutional Review Board on the use of Human Subjects.

Results

Table 3 lists all themes and indicates in which data sources each theme emerged. The response and emergent themes are presented by conceptual domain. All results are presented as they relate to the employee practices in implementing the FDA regulation including making sandwiches according to standardized recipes and answering customer questions about the complete nutrition information of the sandwiches.

Table 3. Resultant themes from all data sources.

Themes		Documents, website, webinars & observation	Employee interviews				Key informant interviews (n=3)
			2015 (n=6)	2016 (n=9)	Count of employees in support of theme	Count of quotations	
ORGANIZATIONAL PRACTICES	**CULTURE OF ORGANIZATION**						
	Health focused [b]	X	X	X	8	31	X
	Customer service focused [b]	X	X	X	15	144	X
	Reliant on collaboration/team work [b]	X	X	X	15	98	X
	INFORMATION DISSEMINATION						
	Organization provided nutrition education [a]	X	X	X	8	24	
	Training on FDA regulation was erratic [a]		X	X	15	177	
	PERFORMANCE MONITORING						
	Sandwich preparation was monitored [b]			X	7	27	X
	Employee knowledge was not evaluated [a]			X	7	17	
EMPLOYEE KNOWLEDGE							
Employees had calorie labeling knowledge [a]			X	X	5	27	X
Calorie labeling was confusing to employees [b]			X	X	6	43	X
Unaware of regulation [a]			X	X	9	18	X
Allergen and food safety knowledge were high [b]			X	X	12	42	X
Aware of nutrition references guides [b]			X	X	7	62	
EMPLOYEE ATTITUDES							
Calorie labeling was confusing to customers [b]		X	X	X	9	66	
Calorie labeling would be helpful for customers [b]		X	X	X	15	80	
High confidence to answer customer questions [a]			X	X	11	34	
Organizational resources enabled high confidence [b]			X	X	11	64	
Nutrition reference guides were helpful [b]			X	X	7	14	
EMPLOYEE PRACTICES							
Bread, meat, and cheese were standardized [b]			X	X	13	90	X
Vegetables and condiments were variable [b]			X	X	11	37	X
Few customers asked questions [a]		X	X	X	13	71	X
Employees had preferred resources [a]			X	X	15	83	

X indicates that the data source supports the theme.

Shaded portions indicate domains and themes not covered by the data source. Unshaded portions are those in which the themes could have arisen.

[a] Response themes arose due to interview questions that specifically asked about the theme.

[b] Emergent themes arose without prompt of interview questions.

Culture of the Organization

EM is a health-oriented supermarket that provides options and information to promote healthy lifestyles. The health-focused culture was characterized by the organization's prioritization of customer and employee health through the promotion of healthful practices and products. Information from data sources that exemplified the organization's orientation toward health of its customers includes convenient, healthy snack coolers and website and in-store resources about special diets. The organization recently installed convenient healthy snack coolers that offered fruit cups, small salads, and fruit and yogurt parfaits, which emerged in one employee interview. The employee discussed the healthy snack coolers to exemplify the health resources that EM provides for customers,

> "They're trying to give a healthy alternative that's just as easy for you to grab and go, to make it easier for everybody to make that adjustment when they're trying to eat healthier." [employee interview]

The EM website included a nutrition webpage with resources that provided information on EM brand products for customers following special diets and included nutrition information on all products prepared in the stores, including the sandwich shop. The availability of the website nutrition resources predated the introduction of the FDA regulation.

Beyond tools and resources available for customers, the organization additionally demonstrated prioritization of employee health. Annual health screenings were held at all locations for employees to meet with pharmacists, registered dietitians (RD), and wellness program staff, and to have height, weight, blood pressure, cholesterol, blood glucose, and other health status indicators measured. One employee described her perspective of the health screenings,

> "For employees, every year they check your blood pressure, your sugar levels, your cholesterol… That type of stuff. Because they want everybody to be healthy." [employee interview]

The organization also employed corporate and regional RDs to implement nutrition programs for employees and customers, and mentored multiple nutrition students each year. Further, the health-oriented culture of the organization is directly related to the implementation of the FDA regulation because the preemptive implementation of the FDA regulation more than two years prior to the May 2018 compliance deadline demonstrates EM's orientation toward health.

Evidence from data sources also indicated a strong organizational focus on customer service within EM. Employees and key informants both described the expectation of high standards of customer service from employees, including the expectation that employees find answers to customer questions. One employee described his customer service orientation as:

> "You're a customer, you have my undivided attention. I will stop and I will take the time every single time. We're only standing behind the counter because they're standing in front of it, so we have to make sure we take the time every time." [employee interview]

Customer service was a major theme that emerged frequently in every employee interview (Table 3), supporting that this was an important aspect of the organizational culture. Moreover, all other data sources reinforced that customer service was central to the culture of the organization. The EM website included a customer service section that exemplified the dedication to customer needs by stating,

> "We want to make sure you have all the information you're looking for… [We] welcome your questions or comments. We'll get back to you as quickly and effectively as possible." [organizational documents]

Data from key informant interviews indicated that in situations in which an employee cannot answer a customer question, that employee was expected to direct the customer to someone who can, or follow-up with the customer at a later time to provide the requested information.

The final theme that emerged in relation to organizational culture is the reliance on collaboration and team work. Employees reported using positive reinforcement to support one another. One employee emphasized that he tries to show his appreciation of his coworkers,

> "For me, I think it's good to appreciate people and let them know that they're appreciated so then they know that they're not just working and they know they're actually doing something for a reason and I think that goes a long way." [employee interview]

Another employee discussed that he received recognition from his peers,

> "When things go the right way I definitely get recognized and try to support people as much as I can and help them out." [employee interview]

The reliance on collaboration and teamwork emerged in all employee interviews with high frequency, indicating its importance in the organizational context.

Information Dissemination

The distribution of menu boards containing calorie information to all EM sandwich shops represents one example of information dissemination, and a description of the menu board layout is necessary for understanding the need for further information dissemination to employees. The menu boards at EM presented the sandwich options by ingredient. The sandwich options were categorized by ingredient heading, with specific ingredients listed under the heading. For example, the menu listed "Condiments" in bold with oil, mayonnaise, mustard, etc. specified beneath. Other ingredient headings included bread, vegetable toppings, cheese, and main filling (meat and vegetarian options). Calories were labeled next to each ingredient and all calories listed on the menu board were based on a sandwich made on standard bread, lettuce and tomato. Each ingredient beyond this sandwich base required addition of calories corresponding to that ingredient. The bread was an exception: because the sandwich base specifies a standard bread, calculation of calories requires addition *or subtraction* of calories from this sandwich base

depending on the bread ordered (e.g. the ciabatta had fewer calories than the standard bread and required subtraction for the caloric content of the sandwich). The standard bread was listed on the menu board with dashes to indicate no additional calories. The addition or subtraction of calories in the bread was specified on the menu board with a plus (+) or minus (-) sign preceding the caloric value.

Employees discussed differing extents to which they received training regarding the FDA regulation. Two employees of fifteen reported that they received training about the calorie labeling in the sandwich shops. Other employees said that they were notified that the sandwich shop had new menu boards specifying calories of menu items, received an email that there were new menu boards, or had no training or communication about the new menu boards. Overall, most employees were unaware of the FDA regulation as the source of the calorie labeling.

Employees discussed varying levels of nutrition education provided by the organization in various formats. One format of the nutrition education was a class about healthy eating patterns taught by a RD, in which a few employees reported participating,

> "We took a class. [The RDs] talked about [EM's] idea of healthy eating and trying to keep everyone healthy." [employee interview]

Other employees mentioned that they had the option of taking a brief computer-based training about nutrition, "There was one online course that I did with nutrition." The last venue in which employees discussed receiving nutrition education was speaking with RDs at health screenings hosted by EM,

> "We have a nutritionist here in the store. And we have fairs every once in a while that we can go to. They set it up like a carnival and you go to the different stations. And one of the stations will be the nutrition." [employee interview]

Of these nutrition education opportunities, none of the education was specifically targeted toward educating employees about the FDA regulation.

Employee Knowledge

Employee knowledge and understanding of calorie labeling was limited. When asked to calculate an example calorie question, six of fifteen employees were within twenty calories (3%) of the correct summation. Of these six employees, only one was able to identify the correct summation of calories, demonstrating that few employees comprehended fully the calorie labeling implementation. Similarly, employees expressed that the way in which calories were noted on the menu boards was confusing and voiced several questions about the format of the menu boards,

> "I actually can't… I don't have a [calorie value] for just roast beef. Would it be this? [pointing to menu board]. That's on white bread. Can I do it for wheat bread?" [employee interview]

In particular, employees expressed confusion about the use of dashes for the caloric value of the white bread, and plus and minus signs preceding the caloric value of other bread,

> "Looking at the dashes on the board, specifically with the white [bread], there's no calorie count on the board whatsoever. It's hard to read because you're trying to add things and subtract things and there's dashes in place of where there should be numbers." [employee interview]

Another employee described similar confusion,

> "We don't understand why there are dashes. There are dashes and then there are just plain blank spaces." [employee interview]

One employee had a more advanced understanding of the boards and described a hypothetical situation in which calculating the calories would be difficult,

> "It gets tricky if you want, like, three meats. Some people want turkey, ham, and capicola. That's not one of the [options]. So, I don't know how I would calculate [the calorie content]." [employee interview]

The pervasive confusion about the display of calories on the menu boards further supports the limited employee knowledge about the calorie labeling.

In interviews with employees, half of the employees were aware of the complete nutrition information available in the nutrition reference guides, and half were unaware. Key informants communicated that employees were expected to be aware of the nutrition reference guides and be able to give customers information about the nutrition of their sandwich using the nutrition reference guides,

> "If it's a regularly available product, [the employees] should be able to provide complete nutrition information within a couple minutes." [key informant interview]

This expectation is reiterated by the FDA regulation, yet half of the employees were not aware of the existence of this information in the sandwich shop. Moreover, most of the employees were unaware of the FDA regulation requiring them to provide complete nutrition information to customers upon request, though all of them were aware of the calorie labeling on the menu boards. Few employees (n=4) identified the FDA regulation as the source of calorie labeling.

Employee Attitudes

Employees discussed how calorie labeling was confusing to customers, yet also sometimes could be helpful. Employees described the customers' confusion about the display of calories on the menu boards,

> "They don't understand how to calculate the calories. It says in the corner 'based off white bread, lettuce, tomato, and something else.' Then they have to do the math and if they're subtracting 70 calories or adding 100, they're confused about that." [employee interview]

Another employee discussed that she explained the menu boards to the customers that expressed confusion,

> "They're confused about what the [menu] boards are saying. That's pretty common and then when we explain it to them." [employee interview]

Despite this confusion, all employees expressed, to varying degrees, that providing calorie information would be helpful for customers,

> "Now they know the calorie intake so, if they're trying to diet or watch their weight, it's easier for them." [employee interview]

Overall, employees had high confidence to answer customer questions, and organizational resources enabled employees' confidence. Most employees reported that they were confident in their ability to answer customer questions accurately regarding the nutrition information about sandwiches. In parallel with this response, most employees stipulated that they were confident due to the resources available to them for answering customer questions including peer employees, supervisors and managers, the nutrition reference guides, and information on the EM website. Employees that were aware of the nutrition reference guides expressed that they were a helpful resource.

To determine if employee knowledge and employee attitudes shifted in the first year of implementation, employee interviews from 2015 (n=6) and 2016 (n=9) were considered separately. The interview responses were all similar in content and therefore no shift in employee knowledge and employee perceptions was identified. The lack of shift in these conceptual domains serves as the justification for combining employee interviews to answer all previous research questions.

Employee Practices

First-level implementation of the FDA regulation required employees to make sandwiches according to standardized recipes. Employees discussed using guards when slicing loaves to ensure that the sandwich bread was the correct length for each sandwich size.

> "We actually have a guard that goes over the bread. You cut the ends off and then each time it will come out the same every time." [employee interview]

The employees elaborated that the meat for each sandwich also was standardized by weight,

> "We have two scales and we're weighing those meats out. To make sure that they get enough or they aren't getting too much." [employee interview]

Finally, employees explained that the cheese was similarly standardized for the sandwiches,

> "The cheese is standard. They usually get 'X' amount of pieces because our cheese is pre-sliced so they weigh the same." [employee interview]

Conversely, employees discussed that there was a suggested quantity of vegetables (tomatoes, cucumbers, lettuce, olives, onions, peppers, pickles, etc.), but that it "all depends on what the customer wants, and that's not going to affect [the cost]." There was less agreement on the guidelines for condiments (mayonnaise, mustard, oil, etc.): one employee described a common belief that,

> "There's no specific amount. Basically, we just want to make sure it's covered from one end to the other. Enough that they get flavor from one end to the other." [employee interview]

Another employee explained, "We're supposed to coat the bread evenly on both sides with the condiments." These employee perspectives indicate that the amount of vegetables and condiments on a sandwich was variable.

Second-level implementation of the FDA regulation required employees to provide complete nutrition information to customers upon request. In order to comply with this requirement, sandwich shop employees undertook a three-step process. Sandwich shop employees first referred to nutrition reference guides to identify each ingredient based on the size sandwich order, then summed the specific nutrient quantities for each ingredient, and finally reported an aggregated number for each nutrient to the customer. This process was supported by evidence from the nutrition reference guides, which contained complete nutrition information

only for individual sandwich ingredients, thereby necessitating employee interpretation as outlined above. Furthermore, key informants explained,

> "[The employees] have to help [customers] figure that out. For example, you have this base and then you have options that you add to it. So, you're building an entire product. It would be easier if we had [the nutrition information] at the point of sale where people could order what they want and as they're ordering it, they just add things on and they see, 'OK that's going to be so many calories.'" [key informant interview]

When asked how often they received customer questions about the nutrition content of sandwiches, most employees reported that very few customers asked questions. One employee discussed that only customers that are unfamiliar with the sandwich shop asked questions,

> "The folks that don't normally come to get sandwiches are the folks that ask the questions, but those are very far and few between. We don't get many of them." [employee interview]

Another employee reflected on the number of questions she received since she was hired, "Every once in a while. I think it's only happened maybe twice in the year I've been here." A third employee had never received any customer questions about nutrition content and had trouble describing how she would answer such a question, "I don't really know [how I would answer] because it hasn't happened." In another situation, an employee described her frequent interactions with a young customer who had a dietary restriction and always required employee help in determining the nutrition content of the sandwich,

> "One little girl has problems with her digestion so she can only have certain amounts of fats every day. She comes in a lot so I always get the binder ready for her…but it's not that common that people ask. It's pretty rare." [employee interview]

Employees elaborated on the resources that they preferred using when answering customer questions. Several employees cited the supervisors and managers as good resources for answering customer questions,

> "I would reach out to a supervisor or manager because the supervisors are trained in every department. So, they would have more information and they know how to handle

customers the appropriate way." [employee interview]

Others discussed the label on the product packaging and the nutrition reference guides as a source for nutrition information,

> "We keep the product on hand and there's labeling on each product... I guess the only two resources that I would use would be the binder or the actual product." [employee interview]

Some employees referred to in-store RDs as one resource, and others described how they would "send an email up to the nutrition department at corporate or phone corporate and get the answer from them." Other utilized resources included peer employees, information on the EM website, and corporate employees. One employee discussed that his favorite resource was the corporate employee that manages all the sandwich shops,

> "We have the manager of all our sub departments. If we wanted to know any information, we can definitely go to him. He knows a lot of that stuff right off the top of his head. He's a really good resource." [employee interview]

Employees cited these preferred resources despite having few customer questions about the FDA regulation.

Monitoring

EM monitored standards of some sandwich components, specifically the bread, meat, and cheese. Employees elaborated that managers monitored the bread baking by checking to make sure the bread loaves were the correct size,

> "I've had managers come over and pull my bread right off [the pan] and stick it right up to [the guide] to check. I've heard of people that come in and if their bread is too long or too high, the managers will make you start all over again." [employee interview]

Data from key informants reinforced the employees' perspectives. One key informant explained that his first task in the morning was to check on the bread and confirm that it was being prepared according to standardized recipes,

> "I inspect the bread every day. It's one of the first things I do when I walk into the department in the morning." [key informant interview]

Pertaining to the sandwich meat and cheese, key informants discussed monitoring practices that were described by employees in accordance with the standardized recipes,

> "We have [specified] weights for our meat and cheese, and we have scales out. They must use those scales." [key informant interview].

Another key informant discussed ways in which he monitored employees to ensure they were following the standardized recipes,

> "We randomly check. There's standardized recipes for the employees to follow and there's people to check on the employees to make sure they're doing things the right way. Sometimes I will order a sub and watch the way they're making it… Are they weighing the meat? Is the sub made right, is it layered right? We do random spot checks frequently." [key informant interview]

Key informants clarified that these practices were previously implemented to reduce waste and increase consistency of products between and within stores, but that now also serve as a form of monitoring for ensuring consistency with printed nutrition information. Furthermore, employees responded that their comprehension of the calorie labeling on menu boards was not evaluated by managers and supervisors, indicating that this was not monitored. Employees were not asked if their ability to provide complete nutrition information was monitored, and this did not emerge in the interviews.

Discussion

The culture of the organization in which the FDA regulation was implemented at EM presented a unique context of strong customer service expectations, widespread health

orientation, and voluntary early implementation of the FDA regulation. The culmination of these organizational characteristics had the potential to meet successfully the high informational needs of health-conscious consumers, who are more likely to notice and use calorie labeling (37–40). This case study suggests that the implementation of the FDA regulation was difficult even in such a motivated and supportive environment.

Information dissemination within the organization was intended to result in the employees following procedures that adhere to the FDA regulation, including making sandwiches according to standardized recipes and providing customers with nutrition information upon request. This case study suggests that information related to the FDA regulation was not adequately transmitted to the employees as evidenced by the lack of employee awareness of nutrition reference guides that contain complete nutrition information, employee confusion regarding calorie labeling, and employees' demonstrated inability to calculate correctly a calorie summation. Two possible explanations for the incomplete transmittal of information are that the organization failed to disseminate the information to employees or the employees received the information but did not understand or apply the information. The reliance on supervisors, managers, corporate employees, and written resources for implementation all suggest that employees did not know the proper implementation practices. By utilizing the knowledge of supervisors and managers, employees deflected implementation rather than engaging in implementation practices themselves. Given the relatively small number of customer questions received, this approach was effective. However, the deflection of implementation to supervisors and managers may not be sustainable if the volume of customer questions increases beyond that which can be accommodated by managers.

Furthermore, some employees were unaware of critical written resources to support their

provision of complete nutrition information to customers. The nutrition reference guides that contained complete nutrition information for all sub ingredients enabled employees to provide customers with complete nutrition information on their sandwich order, making this resource vital to implementation of the FDA regulation. This case study suggests that only half of employees interviewed were aware of the nutrition reference guides. Employees who were unaware of this resource would be unable to provide customers with complete nutrition information of their sandwich, thus they would not be able to implement this aspect of the FDA regulation. Dissemination of information related to critical resources for implementing the FDA regulation is one target for empowering employees to engage in implementation.

Employees inconsistently described how they learned about the calorie labeling required by the FDA regulation, and only two reported receiving specific training about calorie labeling. Given the overall lack of knowledge about calorie labeling combined with little employee training, this case study cannot differentiate between lack of employee training and lack of employee knowledge despite receiving training. However, the potential for lack of employee knowledge despite training is still highly relevant. In food service occupations no post-secondary education is needed, and many entry-level jobs do not require a high school diploma (19). This lack of educational requirements may be at the core of the implementation problem: employees may not be adequately educated to perform tasks related to the FDA regulation such as nutrient computations. Nutrition education may be a fruitful tactic to improve employee knowledge retention and application in the context of low educational attainment. Research has shown that individuals with low nutrition knowledge at baseline were able to apply nutrition education information to change behavior positively (21–24). Results of this case study demonstrated that employees retained knowledge about food safety, allergens, and customer

service on which they were trained, although these themes were emergent and knowledge retention was not objectively measured. Prior evidence about nutrition education and results of this case study suggest that conducting nutrition education training for employees might be similarly effective.

Employees reported that they were confident in their ability to engage in implementation practices, but the objective calorie test demonstrated low ability. Perhaps employees' confidence in their ability to engage in implementation practices is due to the lack of customer questions that test that ability. The dissonance between employee competence and employee confidence that was observed in this case study is similar to what David Dunning and Justin Kruger described in what is known as the Dunning-Kruger effect (41). According to the Dunning-Kruger effect, the skills that enable competence in a particular domain are the same skills that are necessary to evaluate competence in that domain, which leads to an inability of low-competence individuals to assess true competence accurately (41). Without proper skills to assess competence, these individuals overestimate their ability, as this case study demonstrates with sandwich shop employees' reported confidence and tested ability to provide accurate nutrition information (41). Conversely, individuals who have high competence tend to underestimate their ability to perform tasks (41). One employee was a college student studying nutrition who reported having low confidence in her ability to provide accurate nutrition information to customers despite demonstrating high competence in the calorie test. This illustrates the paradox in which gaining skills to improve competence allows an individual to recognize their inadequacies (41).

Performance monitoring of employee practices related to the FDA regulation was effective when it mimicked other organizational practices. These employee practices included making the bread, using the correct amount of meat and cheese on sandwiches, and cutting the

sandwich to the proper size. Key informants noted that these practices were enforced prior to implementation of the FDA regulation at EM and the FDA regulation provided additional justification for following the practices. Conversely, performance monitoring of employee knowledge regarding the calorie labeling and provision of complete nutrition information to customers was lacking. Organizations should explore mechanisms to monitor employee knowledge of calorie labeling and complete nutrition information, without which the justification provided by the FDA regulation for monitoring employee practices is negligible. In order for the integrity of the FDA regulation to be upheld, both employee practices for following standardized recipes and employee knowledge of calorie labeling and complete nutrition information must be monitored to ensure the accuracy of nutrition information provided to consumers.

The paucity of customer questions about the nutrition content of sandwiches was initially puzzling at a health-oriented supermarket that values customer service and has many mechanisms through which customers can ask questions. Evidence suggests that health-conscious consumers, including women, individuals with higher income and education, and those who are pursuing weight loss, are more likely to use calorie labeling than other consumers (37–40). We would expect that these health-conscious consumers request more nutrition information, particularly in a health-oriented food establishment that develops strategies to make asking questions easier. However, the dearth of customer questions suggests that the informational needs of health-conscious consumers may be met in other ways. The demographic characteristics of health-conscious consumers may explain the lack of customer questions: perhaps the higher educational attainment of health-conscious consumers enables them to understand menu labeling better and sum the calories of their order themselves. Moreover, this demographic may be fulfilling their informational needs with the complete nutrition information

on the organization's website, thereby reducing the need to ask questions of the employees. Alternatively, sandwich shop venues may attract few health-conscious consumers due to the nature of the menu items offered, which may explain the low customer demand for nutritional information. The lack of a clear answer about the paucity of customer questions indicates the need for more data from customers' perspectives in future research.

The specifics of the FDA regulation were written in part to minimize human error when information is provided to consumers by requiring provision of written nutrition information (11). The provision of written nutrition information is difficult in the context of made-to-order food establishments in which customers can order countless permutations of menu items. This case study illustrates the limited skill of employees in calculating nutrient composition and employee confusion about the calorie labeling on the menu boards even more than a year after implementation. This suggests that in the absence of adequate information dissemination employees at made-to-order food establishments may not be sufficiently equipped to be answering nutrition questions. Rather, consumers' desire for nutrition information in a made-to-order context presents an opportunity for technology to facilitate the provision of accurate nutrition information in the form of an electronic ordering kiosk (42). With an electronic ordering kiosk, customers type their order into the kiosk, the order is transmitted to employees who make the sandwich, and the kiosk is able to calculate and provide complete nutrition information to the customer. With the use of this technology, employees continue to be responsible for following standardized recipes to ensure that the sandwich corresponds to nutrition information provided at the kiosk, but they no longer need to provide nutrition information to customers. Similar ordering kiosks are in operation at some chain restaurants (43–45), and made-to-order food establishments provide an opportunity for their utility in

implementing the FDA regulation with further reduction of human error in answering nutrition questions.

This case study had several strengths. First, the use of a theoretical framework to guide the research was a notable strength that directed the creation of research questions, the methods and results, and the interpretation of the findings. Second, the research takes place prior to the mandatory implementation of the FDA regulation, during which time food service establishments are developing materials for implementation of menu labeling. The findings of this case study may be helpful to organizations in implementation. Further, this organization's preemptive implementation practices are compliant with the FDA regulation and thus will remain applicable after the mandatory compliance date. Third, the perspective of the participant observer provided extensive knowledge of the organization which informed the context in which implementation occurred. Fourth, the purposive sampling of stores allowed this case study to investigate employee perspectives at stores that served different customer populations, likely covering a wider variety of employee experiences. Finally, the triangulation of multiple data sources contributed to the robustness of the research findings and minimized researcher bias and social desirability bias, discussed below.

There were limitations of this case study that reduce the internal validity of the findings. Researcher bias inevitably manifested in this case study through the selection of the theoretical framework that guided the research, and lingering assumptions, beliefs, values, and biases of the researcher that may have influenced the data collection and interpretation. Researcher bias in the employee and key informant interviews was minimized through use of a semi-structured interview protocol that allowed for previously unconsidered perspectives of employees to manifest and be explored. Social desirability bias was also a concern due to the nature of the

employees discussing their perspectives about a nutrition-related policy with a RD. Employee responses may have been influenced by their desire to express opinions that were concordant with their perceptions of the researcher, and by their desire to be seen as good employees. More specifically, employees may have felt pressured to answer interview questions "correctly"; that is, in a way that they thought is more favorable to the researcher or the employer. Social desirability bias was reduced by asking mostly open-ended interview questions to avoid an indication of a favorable answer. Additionally, the researcher did not disclose her credential as a RD unless directly asked by the participant. Finally, the lack of objective information on employee performance and supervision and data on sandwich making relative to the reported nutrition contents, limits the breadth of the case study.

There were additional limitations for the external validity of the case study, primarily the context of the organization. The organization in which the research took place was health-oriented and customer service-focused. These organizational values may inhibit the generalization of the results to other food service establishments for which these values are not foremost. The effects of the organizational culture on the results of the case study were mitigated by thoroughly describing the organizational context in which data collection occurred and by highlighting attributes of the organization that are common with other food service establishments, such as the made-to-order nature of operations. Finally, the convenience sampling of employees may not have been a representative sample of employees.

This case study described the implementation of the FDA menu labeling regulation in a made-to-order food establishment whose organizational culture valued health and customer service. Within this context, the organization was seemingly well-poised to implement a health-related policy such as the FDA regulation. However, the introduction of new implementation

practices, that included answering customer questions about nutrition content and calculating aggregate statistics for multiple sandwich components, to employees with low educational attainment resulted in substantive barriers to success. Overall, food service establishments may struggle with implementation of menu labeling in the complex made-to-order context, but organizational expectations regarding the ability to respond to customer questions may vary widely. Performance monitoring of sandwich content may effectively build upon commonplace organizational monitoring practices for cost, quality or consistency of products, whereas monitoring of knowledge may require new types of procedures.

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Chapter 3: Discussion and Implications

This case study investigated the implementation of the FDA regulation in a made-to-order food establishment, focusing on the perspectives of the employees with supporting evidence from key informants, organizational documents, and an informal participant observer. In the consideration of the FDA regulation implementation, the employee role in implementation has been examined minimally. The lack of attention to employee perspectives is counterintuitive to the intent of the regulation, which is to provide consumers with accurate nutrition information on menu items when eating out. The employees at food service establishments covered by the regulation are in a position to influence heavily the content of the menu items and the information provided to the consumer, both of which can change the accuracy of the nutrition information. This case study took place in a health-oriented and customer service-focused organization that was seemingly well-poised to implement the FDA regulation. However, results from the case study suggest that employees often were unable to provide customers with accurate nutrition information, thereby interfering with the intent of the regulation.

The research shed light on intriguing matters that warrant further discussion beyond the scope of Chapter 2, including the role of employees as the ultimate policy makers, the use of alternate theoretical frameworks to describe the process of implementing the FDA regulation, and potential future implications of the FDA regulation.

Street-level Bureaucrats

Street-level bureaucrats are workers who enact government policies in the everyday tasks of their jobs, thereby implementing government policy (16). These workers are instrumental in policy implementation because their work activities determine how policies impact the

individuals with which they interact, irrespective of the intention of the policy. In this case study, the employees at EM are street-level bureaucrats due to their involvement in the implementation of the FDA regulation, which aims to provide consumers with accurate nutrition information when eating FAFH (11). These employees implement the FDA regulation through the creation of sandwiches and provision of complete nutrition information, both of which influence the accuracy of the printed nutrition information that corresponds to the sandwich. As such, employees at food service establishments ultimately uphold or undermine the integrity of the FDA regulation, perhaps unknowingly, by engaging in food preparation practices that are congruent or incongruent with label nutrition information. Street-level bureaucrats must integrate the knowledge they have accumulated and apply it to specific situations in a relatively short period of time and without full information (16). As a result, street-level bureaucrats develop coping mechanisms, such as routines and simplification of the nature of their job, to address the problem of doing the job well in the context of limited time and information (16). For employees at EM, knowledge may be derived from formal education, training provided by the organization, and experience on the job, all of which varies by employee. Moreover, employees may develop different coping mechanisms that influence the way in which they complete tasks related to the FDA regulation. The variation in knowledge and application of the policy to specific situations may influence the accuracy of the nutrition information provided to the consumer, thereby impacting the implementation of the FDA regulation. As such, employees at EM and other food establishments covered by the FDA regulation may be the true policy makers in that they ultimately ensure or inhibit the provision of accurate nutrition information to consumers.

Theoretical Framework

This case study was guided by the KAP model of diffusion of innovations theory (28,29). The theory was used to understand the research topic, guide the research questions, develop research methods, and interpret the results within the theoretical framework. The use of the theoretical framework for the understanding and interpretation of the research was a strength of the case study, but also limited its scope and perspective. The use of other theories for the investigation of the FDA regulation implementation might have been useful for a more in-depth description of the theoretical concepts explored within this case study or the elucidation of other concepts. For example, a more in-depth exploration could address employee perspectives about usefulness of the calorie labeling, employee motivation, and role clarity in regulation implementation to gain a deeper understanding of employee attitudes. The use of a Program Impact Pathway (PIP) would be beneficial in understanding the flow of information throughout the process of implementation, and determining the impact of the intervention. A PIP model would allow mapping of what is required at each step in the process and an assessment of what actually occurred. This type of data may be able to provide information about activities that may need to occur to improve the process and maximize the impact, whereas the KAP model of diffusion of innovations enabled a case study description of what is currently happening within the organization. Furthermore, research on employee training and dissemination of innovation would likely benefit from an organizational behavior model to describe the activities and communication in an organization. Research integrating PIP or organizational behavior models, or a combination thereof, would broaden a case study approach, or could support other study designs such as impact assessments. Themes that emerged in this case study that warrant further

investigation are employee motivation and role clarity as they relate to the implementation of the FDA regulation.

Status of FDA Menu Labeling Regulation

The FDA regulation, *Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments* was passed in 2010 as part of the ACA (32). In the seven years following introduction, FDA menu labeling has faced substantive opposition from some sectors of the food industry such as the American Pizza Community, the National Association of Theater Owners, and the National Association of Convenience Stores (34–36). These organizations have urged the FDA to permit exceptions, delay enforcement, and rewrite parts of the regulation to accommodate their preferences. The enforcement date has been delayed twice, the second delay was announced on May 4, 2017, just one day before the enforcement date of May 5, 2017, and another comment period was announced (33). As of this writing, it is not clear what changes will be suggested and incorporated into the regulation, or if the new compliance date of May 7, 2018 will be enforced (33).

Although much of the pressure on the FDA has come from industries who have a financial interest in avoiding the costs of implementation, there also are other concerns about the regulation. An abundance of research has examined the impact of menu labeling on consumer behavior (8,12–15). Several systematic reviews suggest that menu labeling has little to no effect on reducing consumer purchases in a variety of different food service formats with different methods of menu labeling (8,12–15). However, there is evidence that the FDA regulation may be impacting the menus and caloric content of items at food establishments. One study compared differences in caloric content of menu items between food establishments that voluntarily

adopted menu labeling preemptively and those that did not (46). The study found that caloric content of menu items was significantly lower at food establishments that voluntarily displayed calories, although it was unclear whether voluntary labeling motivated the development of lower calorie options or if chain restaurants with lower calorie options were motivated to adopt labeling voluntarily (46). A similar study examined calorie content of menu items at large chain restaurants from 2012 to 2014 and found that newly introduced menu items tended to be lower in calories than pre-existing menu items (47). This research suggests that the FDA regulation is impacting FAFH in a positive and subtle manner: the FDA regulation may be motivating food establishments to offer lower calorie menu items thereby eliciting a change in the food environment for FAFH. Bronfenbrenner's socioecological model has been used to explain the context in which individuals make food decisions (48,49). One variation of the model posits that there are four levels – individual factors, social environment, physical environment, and macro-level environment – that interact to impact eating behaviors directly and indirectly (49). Food service establishments, including made-to-order sandwich shops, exemplify a physical environment in which individuals make food decisions and can act as a target for encouraging behavior change to reduce the risk of obesity and chronic diseases (49). A proposed strategy for influencing the physical environment is enacting policies and legislation at the macro-level (49). The FDA regulation is one such macro-level environment change which may be starting to elicit a change in the physical environment for FAFH (46,47,49).

Conclusion

This case study provides an important first step in examining the FDA regulation from the perspective of the employees who are instrumental to its implementation to answer questions

pertaining to organizational practices, employee knowledge, and employee attitudes as they relate to regulation implementation. The organization presented a unique context of strong customer service expectations, widespread health orientation, and voluntary early implementation of the FDA regulation. In the absence of strong information dissemination, employees were unable to fully implement the FDA regulation and instead relied on knowledgeable managers and supervisors. Performance monitoring of sandwich content may effectively build upon commonplace organizational monitoring practices, whereas monitoring of knowledge may require new types of procedures. There are several remaining questions that were introduced by the research:

- How can organizations monitor employee knowledge and performance regarding calorie labeling and complete nutrition information?
- How do organizational expectations of employees and employee role clarity influence the implementation of the FDA regulation?
- In what ways can human error be reduced in the provision of complete nutrition information at made-to-order food establishments?

Overall, food service establishments may struggle with implementation of the FDA regulation in the complex made-to-order context, but organizational expectations regarding the ability to respond to customer questions may vary widely.

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